Peri-operative Accuracy and Safety of Real Time Continuous Glucose Monitoring System in cardiac surgical patients. A pilot study

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The primary objective of this study is to investigate the peri-operative accuracy and safety of the RT-CGMS in cardiac surgical patients.The secondary objective is to identify and define possible factors interfering with reliable and adequate...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Observational invasive

Summary

ID

NL-OMON29812

Source
ToetsingOnline

Brief title
peri-operative RT-CGMS

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
Hyperglycaemia; blood glucose regulation

Research involving
Human

Sponsors and support

Primary sponsor: Isala Klinieken

Source(s) of monetary or material Support: Medisch Research Fonds

Intervention

Keyword: CGMS, Critical care, Glucose regulation, peri-operative care

Outcome measures

Primary outcome

Correlation between data obtained with the RT-CGMS and the conventional method.

Pairs of data will be analysed using correlation coefficients and Continuous

Glucose Error Grid Analysis.

Adverse effects of the RT-CGMS : irritation of skin, disconnection etc.

Secondary outcome

Degree of glucose control defined as the percent and time of blood glucose measurements in normoglycaemia, hypoglycaemia and hyperglycaemia, as recorded both with sensor measurements and ward measurements; insulin dose; frequency of insulin dose adjustments; time to reach normoglycaemia.

Occurrence of clinical events; hypothermia (Temperature < 36 degrees Celsius), shock (systolic blood pressure<100 mm Hg), acidosis (pH <7.35), other events deemed significant in glucose metabolism and its effect on RT-CGMS.

Other study parameters: sex, age, body weight, body height, BMI, history of diabetes mellitus, presence of risk factors for diabetes mellitus, Severity score, reasons for ICU admission, use of relevant clinical intervention

(nutrition therapy, corticosteroid, vasopressors, etc)

Study description

Background summary

Strict glycemic control improves outcome of patients admitted to the intensive care (ICU). Real Time Continuous Glucose monitoring System (RT-CGMS) is a novel system which can provide health care professionals with real time information about the blood glucose level without the need for multiple invasive measurements. Furthermore, with continuous monitoring it is possible to identify trends in glycemic profiles. Its peri-operative accuracy and safety have never been tested in a population of patients admitted for elictive cardiac surgery.

Study objective

The primary objective of this study is to investigate the peri-operative accuracy and safety of the RT-CGMS in cardiac surgical patients.
The secondary objective is to identify and define possible factors interfering with reliable and adequate glucose measurements and to incestigate its effect on glucose control.

Study design

Open label, randomized controlled trial

Study burden and risks

The RT-CGMS sensor will be inserted once in the abdominal skin. This sensor can stay in situ for 3 days. There is a small risk of skin irritation, infection, haematoma or bleeding involved with the insertion of the sensor.

Because all therapy adjustments will be based on the standard ICU blood glucose protocol, no greater risk of hypoglycaemia is present in the active group than in the control group. The amount of extra glucose measurements in the Active Group will depend on the number of alerts given by the RT-CGMS.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

scheduled for elective cardiac surgery
age over 18
expected stay in hospital > 3 days

Exclusion criteria

failure to obtain informed consent

Study design

Design

Study type:	Observational invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-05-2007
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	25-09-2006
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL12530.075.06